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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 23 1993

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Dicamba (SRR) Registration Standard: Response. PP#4F3041/FAP#4H5428. Dicamba (ID # 55947-38; Potassium Salt) on Grass and Grains. Amendment: Wheat Processing Study. MRID No. 42675901. CBRS NO. 11542. DP Barcode: D189039, D189041 & D189043.

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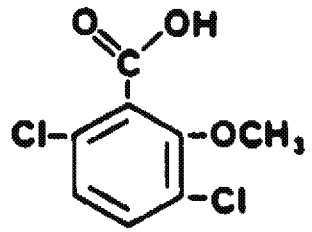
As stated in their letter of 2/19/93, Sandoz submits a wheat processing study in response to our previous review (F. Griffith, 11/4/88, DEB Nos. 3968, 3969, 4018, & 4019) of PP#4F3041/FAP#4H5428 in which a wheat processing study was cited as a data gap because the grain used did not have sufficient residue in the rac before processing.

Dicamba (its structure shown on next page) is on list A for reregistration and is among the list of pesticides for which reviews of processing studies are to be copied to J. Fleuchaus. The Product Chemistry and Residue Chemistry chapters for Dicamba Registration Standard were issued 9/83 and a Second Round Review (SRR) of the Standard was issued 6/89. The SRR document, independent of the 11/4/88 review, cited concentration of dicamba residues (2x) observed in wheat processed fractions (other than flour) based on a previous processing study. More recently,

comments were provided to a draft DCI for dicamba (P. Deschamp, 1/7/92), which removed the grain dust requirement on wheat.

Tolerances are established for the combined residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid in or on wheat grain at 0.5 ppm and wheat straw at 0.5 ppm [40CFR§180.227(a)].



3,6-dichloro-o-anisic acid

CONCLUSIONS

In the current wheat processing study, combined levels of dicamba and 5-OH-dicamba in whole wheat prior to milling were at the tolerance level. Residues of dicamba did not increase in any of the processed fractions. These results are well supported by the recovery data where control samples of wheat fractions were fortified with dicamba and its plant metabolite, each at 0.01 ppm and 0.1 ppm.

RECOMMENDATION

We recommend that the requirement for food/feed tolerances on wheat processed commodities specified in the Dicamba SRR be amended. No food or feed additive tolerances in wheat processed fractions for dicamba are necessary.

DETAILED CONSIDERATIONS

Wheat (Stephens variety) was planted on 10/20/88 at a depth of 1.5 inches with a spacing of 6 inches in a test field located near Jefferson, Oregon. Dicamba, formulated as the potassium salt (Banvel K+SL), was applied with a tractor mounted carbon dioxide sprayer on 7/14/89. The size of control and treatment plots was 10 feet wide by 70 feet long. A 20 foot buffer was left between the two treatment plots and a 220 feet buffer separated the control plot and the treatment plots. The herbicide was applied at either 0.25 lb ai/A or 1.25 lbs ai/A (5x maximum label rate). Application of dicamba to each treatment plot was made about 17-18 inches above the wheat heads (hard dough stage) at a rate of 10 gallons of spray

solution per acre. The wheat was harvested 14 days later (7/28/89) with combine. Samples of wheat were placed in cold storage the same day, shipped under dry ice via Federal Express and reached Sandoz Crop Protection, Des Plaines, IL on 8/1/89.

The wheat samples were processed simulating commercial processing on 1/13/90 at The Texas A & M University System, Food Protein Research and Development Center. Whole wheat was cleaned by aspiration. Water was added to the cleaned wheat kernels to yield a 16% moisture content. The kernels were milled through a series of corrugated and smooth rollers. Between roller millings, the crushed kernels were sieved across different sizes to yield bran, middlings. shorts and germ, red dog, low grade flour and patent flour. The conditioning and milling procedure used was equivalent to the American Association of Cereal Chemists (AACC) method 26-21. Samples of processed wheat commodities (1 or 2 lbs each) generated from control and treated (at 5x rate) wheat kernels were shipped frozen to Sandoz Crop Protection Corporation on 1/24/90 and kept frozen until residue analyses in late April or early May of 1990.

Wheat and its processed fractions were analyzed by "Determination of Dicamba and 5-hydroxy Dicamba Residues in Barley, Corn, Cotton Processing Fraction, Pasture Grass, Peanut, Sorghum, Soybean, Sugar Cane, Tomato, Tomato Processed Fractions, Wheat and Wheat Processed Fractions (GC)", coded method AM-0691B, with minor modifications. Detector used is either EC or HECD. The modifications included cooling hydrolysate, skipping solvent volume adjustment, lower activation temperature for silica gel column, GC column substition, and adjusting GC operating conditions. Our 11/4/88 review concluded that AM-0691B is suitable to measure and enforce levels of dicamba and 5-OH-dicamba in grass and grains (except cotton). AM-0691B hydrolyzes conjugates, esters and ethers of dicamba and 5-OH-dicamba, and converts the hydrolysates to methyl ester of dicamba and 5-methoxydicamba.

Levels of dicamba and its 5-OH metabolite in various wheat fractions and concurrent recoveries are tabulated below.

Table 1. Results of Wheat Processing Study*.

	Treated at 1.25 lbs ai/A		% rec at 0.01 & 0.1 ppm	
	Dicamba	5-OH (ppm)	Dicamba	5-OH
Whole wheat	0.440	0.034	110, 101	110, 100
Bran	0.436	0.037	70, 88	110, 86
Middlings	0.070	<0.01	90, 93	110, 84
Shorts & germ	0.236	0.030	80, 87	100, 79

Patent flour	0.023	<0.01	70, 95	110, 92

Control samples of wheat and wheat fractions contained <0.01 ppm dicamba and <0.01 ppm 5-OH-dicamba.

Since the processed wheat samples were stored for about 4 months before residue analysis, the registrant cited a storage stability study conducted as part of the last wheat processing study in MRID # 40663801. Our 11/4/88 review concluded that dicamba and its 5-OH metabolite are stable in wheat flour, germ and shorts under frozen storage for 4 months. Therefore, no corrections of dicamba or its metabolite level in any of the processed fractions are needed.

It is evident from the results shown in Table 1 that combined residues of dicamba and its 5-hydroxylated metabolite did not concentrate in any of the wheat processed fractions. Combined levels of dicamba and 5-OH-dicamba in whole wheat prior to milling were at the tolerance level which led to measurable residues in all the processed fractions. These results are well supported by the recovery data where control samples of wheat fractions were fortified with dicamba and its plant metabolite, each at 0.01 ppm and 0.1 ppm.

The treated whole wheat used in the previous processing study (and reviewed in the 11/4/88 memo) bore 0.021-0.029 ppm of dicamba, a level that is 2-3x the limit of detection of 0.01 ppm, and bore <0.01 ppm 5-OH-dicamba. While processing results showed an increase of dicamba level up to 2x in the bran, germ and shorts fractions, there were no validation data at the 0.01 ppm level to support the processing study results; all the method validation data were conducted at 0.1 ppm dicamba and higher. A proper processing study should be conducted with a rac bearing residues at the tolerance or a significant level.

Thus, no food or feed additive tolerances in wheat processed fractions for dicamba are necessary.

cc:Circ, RF, Reg Std File, PP#4F3041/FAP#4H5428, Cheng, Fleuchaus (LE-132P)
RDI:FSuhre:4/22/93:MMetzger:4/22/93:EZager:4/23/93
H7509C:CBRS:LCheng:CM#2:RM804/810D:4/21/93:03:DICAMBA\WHEATPRO

DICAMBA (CASE 65) RESIDUE CHEMISTRY DATA SUMMARY THROUGH 4/21/93[1]

REASSESSMENT OF U.S. TOLERANCES AND POTENTIAL FOR HARMONIZATION WITH CODEX[2]

Guideline Number and Topic[3]	Phase V data requirements satisfied?	MRID(s)[4]
171-3 Directions for use		
171-4(a) Plant Metabolism	Y[5]	
171-4(b) Animal Metabolism	N	
171-4(c) Residue Analytical Methods - Plants	N	
171-4(d) Residue Analytical Methods - Animals	N	
171-4(e) Storage Stability	N	
171-4(k) Crop Field Trials	--[6]	
171-4(k) Legume Vegetables (succulent/dried)		
Soybeans [see 171-4(l)]	Y	
171-4(k) Foliage of Legume Vegetables		
Soybean forage and hay	Y	
171-4(k) Cereal Grains Group		
Barley [see 171-4(l)]	N	
Corn (field) [see 171-4(l)]	Y	
Millet [see 171-4(l)]	N	
Oats [see 171-4(l)]	N	
Sorghum [see 171-4(l)]	N	
Wheat [see 171-4(l)]	N	
171-4(k) Forage, Fodder, and Straw of Cereal Grains		
Barley forage and straw	N	
Corn forage and fodder	Y	
Millet forage and straw	N	
Oats forage and straw	N	
Rye forage and straw	N	
Sorghum forage and fodder	N	
Wheat forage and straw	N	
171-4(k) Grass Forage, Fodder, and Hay Group		
Pasture/rangeland grasses	N	
171-4(k) Miscellaneous Commodities		
Asparagus	N	
Sugarcane [see 171-4(l)]	Y	
171-4(l) Processed Food/Feed		
Barley	Y	
Corn, field	Y[7]	41187301
Millet	Y	
Oats	Y	
Rye	Y	
Sorghum, grain	N	
Soybeans	Y	
Sugarcane	N	
Wheat	Y[8]	42875801
171-4(j) Meat/Milk/Poultry/Eggs	Reserved	

DICAMBA (CASE 65) RESIDUE CHEMISTRY DATA SUMMARY THROUGH 4/21/93[1]		
REASSESSMENT OF U.S. TOLERANCES AND POTENTIAL FOR HARMONIZATION WITH CODEX[2]		
Guideline Number and Topic[3]	Phase V data requirements satisfied?	MRID(s)[4]
171-4(f) Potable Water	N/A	
171-4(g) Fish	N/A	
171-4(h) Irrigated Crops	N/A	
171-4(i) Food Handling Establishments	N/A	
171-5 Reduction of Residues	N/A	

[1]Second Round Review (SRR) Registration Standard issued 6/89. See CBRS Comments dated 1/7/92 for a 48-hour Draft DCI.

[2]No Codex MRLs exist for residues of dicamba in/on food/feed items. Therefore, there are no questions of compatibility with respect to the U.S. tolerances and Codex MRLs.

[3]N/A = Guideline requirement not applicable.

[4]MRIDs that were reviewed in the current submission are designated in shaded type.

[5]The qualitative nature of the residue in plants is adequately understood. The residues of concern in or on plant commodities are dicamba and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid (40 CFR §180.227[a], §185.1800, and §186.1800), except in or on asparagus, soybeans, and soybean forage and hay. The residues of concern in soybeans and soybean forage and hay (40 CFR §180.227[b]) and asparagus are dicamba and its metabolite 3,6-dichloro-2-hydroxybenzoic acid.

[6]Refer to CBRS comments dated 1/7/92 on a 48-hour DCI review. Data from side-by-side trials with SC/L formulations containing the potassium (K), dimethylamine (DMA), and diglycolamine (DMA) salts were required for asparagus, grasses (forage/fodder), sorghum grain, sorghum (forage/fodder), and wheat (forage/fodder).

[7]CBRS Nos. 8592, 8593, and 9190 dated 4/3/92 by P. Deschamp. Data from a corn grain processing study indicate that residues do not concentrate in corn processed products. No food/feed additive tolerances are required.

[8]CBRS No. 11542 (L. Cheng, 4/23/93). Data from a wheat grain processing study indicate that residues do not concentrate in wheat processed products. No food/feed additive tolerances are needed.

cc: L. Cheng; Reregistration Standard File for Dicamba; Lois Rossi (SRRD)
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